UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES ex rel.	)	
PHILIP HESS,[1]	)	
Bringing this action on behalf of	)	
the United States Government,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 4:05CV570MLM**
	)	
SANOFI-SYNTHELABO INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

This matter is before the court pursuant to the Motion to Dismiss under Federal Rules of Civil Procedure 12(b)(6) and 9(b) filed by Defendant Sanofi-Synthelabo, Inc. ("Defendant"). Doc. 15. Plaintiff Philip Hess ("Realtor" or "Plaintiff") has filed a Response. Doc. 19. Defendant has filed a Reply. Doc. 21. The parties have consented to the jurisdiction of the undersigned United States Magistrate Judge pursuant to 28 U.S.C. § 636(c). Doc. 22.

BACKGROUND

Plaintiff filed the *qui tam* action under consideration on April 11, 1005. Doc. 1. The matter remained sealed until November 9, 2005, at which time the Government elected not to intervene. Doc. 8. Plaintiff's Complaint alleges that he was employed as a sales representative by Defendant

[1] Plaintiff has pending a second cause of action against Defendant alleging wrongful discharge and tortious interference with business relations and business expectations. Case No. 4:05CV2195MLM.

from October 2001 to April 28, 2004[2] and that Defendant is a pharmaceutical company. Plaintiff's *qui tam* action is brought pursuant to the False Claims Act ("FCA"), 31 U.S.C. §3729-33, and addresses Defendant's promotion and marketing of certain prescription medications.

The Food, Drug and Cosmetics Act ("FDCA") governs the distribution in interstate commerce of prescription medications. In Parke-Davis, 147 F. Supp.2d at 44-45, also a *qui tam* action, the court set forth the provisions the FDCA applicable to the matter under consideration as follows:

> Under the [FDCA], 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the [FDA] that the drug is safe and effective for each of its intended uses. See 21 U.S.C. § 355(a) & (d). Once a drug is approved for a particular use, however, the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA. Allowing physicians to prescribe drugs for such "off-label" usage "is an accepted and necessary corollary of the FDA's mission to regulate [pharmaceuticals] without directly interfering with the practice of medicine." Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 121 S.Ct. 1012, 1018, 148 L.Ed.2d 854 (2001). Though physicians may prescribe drugs for off-label usage, the FDA prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. See 21 U.S.C. § 331(d) (prohibiting distribution of drug for non-approved uses); id. § 331(a) (prohibiting distribution of a "misbranded" drug). A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about its unapproved uses. See Washington Legal Foundation v. Henney, 202 F.3d 331, 333 (D.C.Cir.2000). If the manufacturer intends to promote the drug for new uses in addition to those already approved, the materials on off-label uses must meet certain stringent requirements and the manufacturer must resubmit the drug to the FDA testing and approval process. Id. at 334 (setting forth the requirements in the Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 360aaa, et seq.)
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> Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program. Reimbursement under Medicaid is, ***in most circumstances***,

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[2] In his Complaint Plaintiff alleges that he worked for Defendant until February 2004. In the affidavit in support of his Response to the Motion to Dismiss Plaintiff states that he worked for Defendant until April 28, 2004.

> available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." Id. § 1396r-8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. Id. §1396r-8(k)(6). See also id. § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

(emphasis added).

Plaintiff alleges that Defendant manufactures the pharmaceutical drug Eloxatin which was approved in August 2002, by the FDA for second line treatment of fourth stage colorectal cancer; that while Plaintiff was employed by Defendant, Defendant provided Plaintiff and other sales representatives with training on off-label[3] uses of Eloxatin and with training on how to get Medicare reimbursement for off-label uses of Eloxatin; that in November 2002, Wisconsin Physician Services ("WPS"), the Medicare administrator for the States of Illinois, Wisconsin, Minnesota, and Michigan, added Eloxatin to its policy with broad coverage for the treatment of colorectal cancer with Eloxatin, including treatment in the first line and adjuvant setting even though these were off-label uses; that in January 2004, the FDA approved Eloxatin for treatment in the first line setting after Defendant submitted a Supplemental New Drug Application for this use; and that in November 2004, the FDA approved Eloxatin for treatment in the adjuvant setting after Defendant submitted a Supplemental New Drug Application for this use.

Plaintiff also alleges that in July 2002 the FDA approved Defendant's drug, Elitek for the

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[3] As stated above in United States ex rel. Franklin v. Parke-Davis, Division of Warner-Lambert Co., 147 F. Supp.2d 39, 44 (D. Mass. 2001),"off-label" uses of prescription drugs are uses "which are different than those approved by the FDA."

treatment and prevention of tumor lyses syndrome ("TLS") in pediatric patients; that Defendant's FDA application for adult treatment had been turned down; and that beginning in February 2004 Defendant trained Plaintiff and other sales representatives on off-label uses of Elitek in adult patients and encouraged them to promote off-label sales of Elitek.

Plaintiff basis his FCA cause of action on the following: (1) that by promoting the off-label uses of Eloxatin and Elitek to physicians by using immature, unreliable, and misleading clinical data, Defendant caused WPS to authorize Medicare coverage for off-label use; (2) that Defendant knowingly caused to be presented to an officer or employee of the United States Government (the "Government") false or fraudulent claims for payment or approval in violation of the FCA, 31 U.S.C. § 3729(a)(1); (3) that Defendant knowingly made, used or caused to be made or used, false records or statements to get false or fraudulent claims paid in violation of 31 U.S.C. §3729(a)(2); (4) that Defendant conspired with private physicians and other health care providers to defraud the Government by getting false and/or fraudulent Medicare claims paid in violation of the FCA, 31 U.S.C. § 3729(a)(3); (5) that Defendant encouraged the actions of its various officers, agents, and employees to take the actions set forth above and that as a result the Government reimbursed physicians for treatments that it otherwise would not have had Defendant not presented false or misleading information to the physicians in an effort to promote off-label uses; (6) that the Government has sustained damages as a result of Defendant's violations of the FCA; and (7) that Defendant knowingly violated the FCA.

LEGAL STANDARDS

A court may dismiss a cause of action for failure to state a claim if it appears beyond a doubt that the plaintiff can prove no set of facts in support of its claim that would entitle it to relief. Conley

v. Gibson, 355 U.S. 41, 45-46 (1957); Alexander v. Peffer, 993 F.2d 1348, 1349 (8th Cir. 1993). "The issue is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support [its] claim." Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). See also Bennett v. Berg, 685 F.2d 1053, 1058 (8th Cir. 1982) (a complaint should not be dismissed merely because the court doubts that a plaintiff will be able to prove all of the necessary factual allegations). The court must review the complaint most favorably to the plaintiff and take all well-pleaded allegations as true to determine whether the plaintiff is entitled to relief. Conley, 355 U.S. at 45-46. A dismissal under Rule 12(b)(6) should be granted only in the unusual case in which a plaintiff has presented allegations that show on the face of the complaint that there is some insuperable bar to relief. Coleman v. Watt, 40 F.3d 255, 258 (8th Cir. 1994).

Qui tam actions under the FCA "must be pled with particularity pursuant to Rule 9(b)" of Federal Rules of Civil Procedure. United States ex rel. Costner, 317 F.3d 883, 888 (8th Cir. 2003). See also United States ex rel. Joshi v. St. Luke's Hospital, Inc., 2006 WL 522195, at *3 (8th Cir. March 6, 2006); United States ex rel. Schuhardt v. Washington Univ., 228 F. Supp.2d 1018, 1034 (E.D. Mo. 2002). Rule 9(b) the Federal Rules of Civil Procedure requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Under Rule 9(b), the term "circumstances" includes "such matters as the time, place and contents of false representations, as well as the identity of the person making the misrepresentation and what was obtained or given up thereby." Parnes v. Gateway 2000, Inc., 122 F.3d 539, 549 (8th Cir.1997) (quoting Commercial Prop. Invs., Inc. v. Quality Inns Int'l, Inc., 61 F.3d 639, 644 (8th Cir.1995)). "Particularity" means "the who, what, when, where and how: the first paragraph of any newspaper story." DiLeo v. Ernst & Young, 901 F.2d 624, 627-628 (7th Cir. 1990). See also Costner, 317 F.3d

at 888. Thus, the particularity requirement of Rule 9(b) "demands a higher degree of notice than that required for other claims" and "is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations." Id. (citing Abels v. Farmers Commodities Corp., 259 F.3d 910, 920-21 (8th Cir. 2001)).

A complaint must be specific "'enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong.'" Id. at 889 (quoting United States ex rel. Lee v. SmithKline Beecham Inc.., 245 F.3d 1048, 1051-52 (9th Cir. 2001)). Rule 9(b) requires more than "conclusory and generalized allegations." Joshi, 2006 WL 522195, at *3(citing Schaller Tel. Co. v. Golden Sky Sys., Inc., 298 F.3d 736, 746 (8th Cir. 2002) ("'[C]onclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy [Rule 9(b)].'") (quoting Commercial Prop. Inv. v. Quality Inns, 61 F.3d 639, 644 (8th Cir. 1995). "The requirements of Rule 9(b), however, must be read in conjunction with Fed. R.Civ. P. 8(a), which requests 'a short and plain statement of the claim' for relief. Thus, while Realtor must allege the circumstances of fraud, he is not required to plead all of the evidence or facts supporting it." United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co., 147 F.Supp.2d 39, 45 (D. Mass. 2001).

DISCUSSION

A. Legal Framework of the FCA, 31U.S.C. § § 3729(a)(1)-(3):

In its Motion to Dismiss Defendant alleges that Plaintiff's Complaint fails to plead facts that would establish the necessary elements of a claim under the FCA and fails to allege fraud with the required particularity. In support of this position Defendant contends that despite conceding that the relevant Medicare carrier exercised its authority to cover Eloxatin beyond the second line setting,

Plaintiff claims that Defendant violated the FDA by promoting Eloxatin to doctors for use beyond the second line setting. In particular, Defendant contends that Plaintiff does not allege that Defendant made any misrepresentations to doctors, to the Government or to anyone regarding Eloxatin; that Plaintiff does not allege a single doctor prescribed Eloxatin improperly; that Plaintiff does not allege that any doctors who may have prescribed Eloxatin and sought reimbursement from Medicare made any misrepresentations to Medicare; and that Plaintiff concedes that Medicare does not require physicians to specify the stage for which they are using a cancer drug. In its Motion to Dismiss Defendant also contends, in regard to Elitek, that Plaintiff does not allege that Defendant's training in off-label uses of this medication was untruthful or deceitful.

In addition to alleging that Plaintiff's pleadings are factually insufficient, Defendant contends that Plaintiff's Complaint is legally insufficient because there is no case law to support its theory of liability under the FCA.

The FCA, 31 U.S.C. § 3729 provides as follows:

> **a) Liability for certain acts.**--Any person who--
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> **(1)** knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> **(2)** knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
>
> **(3)** conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> ...
>
> is liable to the United States Government for a civil penalty ... .
>
> **b) Knowing and knowingly defined.**--For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information--

> **(1)** has actual knowledge of the information;
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> **(2)** acts in deliberate ignorance of the truth or falsity of the information; or
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> **(3)** acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.
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> **c) Claim defined.**--For purposes of this section, "claim" includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

The Eighth Circuit has recently held that "[t]he [FCA] is intended to encourage individuals who are either close observers or involved in [ ] fraudulent activity to come forward, and is not intended to create windfalls for people with secondhand knowledge of the wrongdoing.'" Joshi, 2006 WL 522195, at *7 (citing Kinney v. Stoltz, 327 F.3d 671, 674 (8th Cir. 2003)). In Costner, 317 F.2d at 886, the court explained that the FCA "imposes liability on '[a]ny person who ***knowingly*** presents, or causes to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval.'" (emphasis added) (quoting 31 U.S.C. § 3729(a)). The court further noted "that the falsehood in a claim must be ***material*** to the payment decision." Id. (emphasis added). See also Rabushka ex rel. United States v. Crane Co., 122 F.3d 559, 563 (8th Cir. 1997) ("To prove his claims under the FCA, [a plaintiff] must show that a claim for payment from the government was made and that the claim was 'false or fraudulent'") (citations omitted); Washington Univ., 228 F. Supp.2d at 1023 ("To state a claim under the FCA [§3729(a)(1)] a plaintiff is required to establish: (1) that the defendant submitted a claim for payment to the federal government; (2) the claim was false or fraudulent; and (3) the defendant submitted the claim 'knowing' that it was false or fraudulent.") (citing Rabushka ex rel. United States v. Crane Co., 122

F.3d 559, 563 (8th Cir.1997)).

In regard to the intent requirement of the FCA the Eighth Circuit held in Costner, 317 F.2d at 887-88:

> "[I]f the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim." United States ex rel. Becker v. Westinghouse Savannah River Co., 305 F.3d 284, 289 (4th Cir.2002) (quoting United States ex rel. Durcholz v. FKW, Inc., 189 F.3d 542, 543 (7th Cir.1999)). A contractor that is open with the government regarding problems and limitations and engages in a cooperative effort with the government to find a solution lacks the intent required by the Act. United States ex rel. Butler v. Hughes Helicopters, Inc., 71 F.3d 321, 327 (9th Cir.1995) (citing Wang ex rel. United States v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir.1992)).

In court further addressed the materiality requirement of the FCA in Costner and stated as follows:

> The existence of and appropriate standard for a materiality element is a matter of some disagreement in the courts. See, e.g., United States, ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 415-16 (3d Cir.1999) (declining to decide whether such an element exists because the claims at issue would easily qualify); United States v. Southland Mgmt. Corp., 288 F.3d 665, 674- 78 (5th Cir.) (questioning existence of materiality element, but finding that false certification of compliance with condition required for payment satisfied even strict outcome materiality standard), reh'g en banc granted, 307 F.3d 352 (5th Cir.2002); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 785 (4th Cir.1999) (applying materiality requirement that depends on "whether the false statement has a natural tendency to influence agency action").
>
> Although we have not heretofore directly considered whether a materiality element is implicit in the Act, we have stated that the Act provides recovery from one "who makes a material misrepresentation to avoid paying some obligation owed to the government." United States v. Q Int'l Courier, Inc., 131 F.3d 770, 772 (8th Cir.1997). Moreover, our decision in Rabushka ex rel. United States v. Crane Co. suggests that outcome materiality is the proper standard. 122 F.3d 559, 563 (8th Cir.1997) ("If Rabushka cannot show that the PBGC would have terminated CF & I's pension plan [if it had known of the misrepresentations and nondisclosures], then there is no false claim because ... liabilities would have occurred regardless of Crane's

> actions."). In our prior decision in this case we implied a materiality standard stricter than mere relevancy: "only those actions by the claimant which have the purpose and effect of causing the United States to pay out money it is not obligated to pay ... are properly considered 'claims' within the meaning of the FCA." Costner I, 153 F.3d at 677.

Id. at 886-87.

B. Allegations of Plaintiff's Complaint Relevant to Elitek:[4]

In regard to Elitek, the only factual allegations which Plaintiff makes in support of his claims pursuant to the FCA, 31 U.S.C. § § 3729(a)(1), (2), and (3), are that beginning in February 2004 Defendant trained Plaintiff and other sales representatives and encouraged them to promote off-label uses of this medication. Plaintiff further alleges that Defendant pressured its sales representatives to derive a substantial amount of sales from the off-label use of Elitek. Compl., ¶ ¶ 30-34. The affidavit which Plaintiff submits in support of his opposition to Defendant's Motion to Dismiss does not provide greater detail regarding Defendant's allegedly unlawful conduct involving Elitek. Doc. 19, Ex. A.

Rule 9(b) requires that a complaint allege the who, what, when, where, and how of fraud. Joshi, 2006 WL 522195, at *3; DiLeo, 901 F.2d at 627-28. Plaintiff fails to allege the who, what, when, where, and how regarding Defendant's sales representatives allegedly promoting the off-label uses of Elitek to doctors nor does he makes such allegations regarding Defendant's allegedly training its sales representatives in off-label uses of Elitek. Significantly, Plaintiff does not plead the time or

[4] Defendant's Motion to Dismiss addresses Plaintiff's Complaint in its entirety although Defendant does not go into great detail in its Motion to Dismiss regarding Elitek. Defendant does state that Plaintiff's Complaint does not allege that Defendant's training for off-label uses of Elitek contained untruthful or deceitful information. Doc. 16 at 6. As such, the court will consider Plaintiff's allegations relevant to Elitek pursuant to its consideration of Defendant's Motion to Dismiss.

place of the allegedly false representations regarding Elitek. Parnes, 122 F.3d at 549. Moreover, he does not allege the nature or content of claims made which were allegedly fraudulent. Joshi, 2006 WL 522195, at *3 (affirming the district court's finding that pleadings were insufficient where the Complaint failed to allege, among other things, "what the content was of the fraudulent claims"). Under such circumstances, the court finds that Plaintiff's allegations in regard to Elitek fail to give Defendant sufficient notice of the particular misconduct which Plaintiff alleges is fraudulent in violation of the FCA. See Parke-Davis, 147 F.Supp.2d at 50 (finding a complaint alleging a pharmaceutical company's illegal promotion of a prescription medication insufficient under Rule 9(b) where the complaint failed to "identify the liaisons involved in the fraud, the doctors who were given false information, or any false claims made"). Also, because Plaintiff fails to allege that doctors to whom Plaintiff promoted off-label use of Elitek actually submitted false claims to the Government for off-label uses of this prescription drug, Plaintiff does not allege facts which would entitle him to relief on his claims pursuant to 31 U.S.C. § 3729(a)(1)-(3). Rule 12(b)(6). Plaintiff's allegations in regard to Elitek are vague, conclusory, and lack the requisite specificity to withstand a motion to dismiss pursuant either Rule 12(b)(6) or Rule 9(b). The court finds, therefore, that Defendant's Motion to Dismiss under Federal Rules of Civil Procedure 12(b)(6) and 9(b) should be granted in regard to allegations involving Elitek.

C. Allegations of Plaintiff's Complaint regarding Eloxatin:

In regard to the requirements for a violation of the FCA relating to Defendant's promotion of off-label uses of Eloxatin to its sales representatives who in turn allegedly promoted this drug to physicians who in turn allegedly sought medicare reimbursement for their prescription of Eloxatin for off-label uses, the court will assume that Plaintiff's Complaint meets the requirement that claims were

made to the Government; physicians did file claims for Medicare reimbursement. See United States v. Taber Extrusions, LP, 341 F.3d 843, 845 (quoting United States ex rel. Quirk v. Madonna Towers, Inc., 278 F.3d 765, 767 (8th Cir. 2002) (holding that § 3729(a)(1) is "broad enough to 'reach any person who knowingly assisted the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government '"); Parke-Davis, 147 F.Supp.2d at 48.

The court will first address the materiality requirement of the FCA. As stated above, to state a valid claim pursuant to the FCA a defendant must make a material misrepresentation. This false statement must have a natural tendency to influence agency action. Costner, 317 F.3d at 887-88. Indeed, drug manufacturers are ***not prohibited*** from ***promoting*** off-label uses of medications if they "meet certain stringent requirements" and if they "***resubmit the drug to the FDA*** testing and approval process." Parke-Davis, 147 F.Supp.2d at 44. (emphasis added).[5] Plaintiff contends, however, that his claim arises because, as a result of Defendant's off-label promotion, doctors submitted Medicare reimbursement claims for uses which the Government did not intend to reimburse. As such, to fulfill the materiality requirement of the FCA Plaintiff must allege with the required specificity, among other things, that: (1) Defendant ***fraudulently promoted*** certain off-label uses of Eloxatin to doctors; (2) that these doctors submitted Medicare claims for off-label uses of Eloxatin and (3) that these claims were a result of Defendant's promotion of such off-label uses. Parke-Davis, 147 F.Supp.2d at 52. In other words, Plaintiff must plead that but for Defendant's allegedly fraudulent misrepresentations the

[5] FDCA permits doctors to prescribe off-label usage of prescription medication. Parke-Davis, 147 F.Supp.2d at 44. However, in most circumstances Medicare will not reimburse them for prescribing such medication. Id.

doctors would not have made claims to Medicare for off-label uses of Eloxatin and that but for these allegedly fraudulent misrepresentations Medicare would not have reimbursed the doctors.

According to Plaintiff's Complaint, ¶ 13, although "the Medicare claim form has a line for indicating the patient's diagnosis," it "does not require a doctor to indicate what stage cancer the patient has." As such, the stage of a patient's cancer is not material to a doctor's seeking reimbursement for his or her prescribing Eloxatin for treatment of cancer. The stage of a patient's cancer, therefore, was not material to WPS in making a decision to reimburse doctors for their prescription of Eloxatin. Thus, assuming all of the allegations of Plaintiff's Complaint as true, under no circumstances can Plaintiff prove facts to support his claim that Defendant violated the FCA by promoting off-label uses of Eloxatin to physicians who in turn sought Medicare reimbursement for these off-label uses. Rule 12(b)(6). The court finds, therefore, that Plaintiff has insufficiently plead the materiality requirement of the FCA in regard to Defendant's alleged promotion of and causing doctors to prescribe Eloxatin from October 2001 through April 2004. Fed. R. Civ. P. 9(b).

Also, in regard to the materiality requirement of the FCA, if the Government knew of problems that Defendant and/or doctors had with claims for Medicare reimbursement for off-label uses of Eloxatin and if the Government worked with Defendant and/or the doctors to find a solution, Plaintiff will be unable to prove all of the necessary factual allegations to establish a violation of the FCA. Scheuer, 416 U.S. at 236; Costner, 317 F.3d at 887. Plaintiff alleges, in regard to Eloxatin, that in August 2002 Eloxatin was initially approved by the FDA for fourth stage colorectal cancer; that in July 2003 Defendant submitted a supplemental application to the FDA for use of Eloxatin in first-line settings; that in January 2004 the FDA approved Eloxatin for treatment in first-line settings; that in January 2004 Defendant submitted a supplemental application to the FDA for use of Eloxatin

in adjuvant settings; and that in November 2004 the FDA approved Eloxatin in adjuvant settings.[6] Compl., ¶ ¶ 15, 26-28. Under such circumstances Defendant was open with the Government regarding its intentions to market Eloxatin in first line and adjuvant settings. Costner, 317, F.3d at 887-88.

The court will next consider, arguendo, whether Plaintiff has sufficiently pled the intent requirement of the FCA. In support of Plaintiff's allegation that Defendant fraudulently or falsely promoted Eloxatin to doctors, Plaintiff alleges that Defendant provided its sales representatives with information which was neither published nor complete; that it urged doctors to contact WPS to encourage the broadest Medicare coverage for Eloxatin; that it provided sales representatives with training in off-label data for Eloxatin and gave them computers which included such data; that it told its sales representatives to show doctors the data in the computers if the doctors asked about off-label uses for Eloxatin; that it provided sales representatives with sales goals which were impossible to meet without off-label use; that it encouraged sales representatives to use the Drug Assistance Program ("DAP") to provide Eloxatin in the event a doctor did not get reimbursement for off-label use; and that it gave sales representatives monographs which contained information on the adjuvant and first line trials for Eloxatin. Further in regard to the intent requirement, Plaintiff merely alleges that data which Defendant provided to doctors was "immature and unreliable" and "immature, unreliable, and misleading." Compl., ¶ ¶ 15, 34. Also, in an affidavit, Plaintiff states that a trial which

[6] The court notes, as set forth above, when a drug manufacturer intends to promote a drug for uses other than approved uses, the manufacturer must resubmit the drug to the FDA for testing and approval. Parke-Davis, 147 F.Supp.2d at 44. Upon filing supplemental applications, as alleged by Plaintiff, Defendant was following proper procedure pursuant to the FDCA. Parke-Davis, 147 F.Supp.2d at 44.

compared Eloxatin with another medication for first line treatment of colorectal cancer "was a complex study [sic] there were serious questions about the study design." Doc. 19, Ex. A, ¶ 33. Plaintiff does make conclusory allegations that the Medicare claims made by doctors were false or fraudulent and that Defendant caused these claims to be made, but these conclusory allegations fail to meet the pleading requirements of Rule 9(b). Compl, ¶ 35, 36, 37, 39. See Parke-Davis, 147 F.Supp.2d at 46 ("To pass Rule 9(b) muster, the complaint must plead with *particularity* the ... contents of the false representations.") (emphasis added).

Plaintiff also alleges that Defendant provided doctors with information about clinical trials involving off-label uses and asked doctors to write a letter to WPS urging the broadest coverage for Eloxatin. In his affidavit Plaintiff states that the medical director for the WPS "admonished" Defendant for the letter writing campaign. Doc. 21, Ex. A, ¶ 40. As discussed above, merely providing information does not violate the FDCA.

Plaintiff neither alleges that Defendant deliberately lied nor that the data provided by Defendant either to its sales representatives or to doctors was incorrect or false. See Costner, 317 F.3d at 887-88. Plaintiff merely alleges that Defendant provided others with information regarding off-label uses of Eloxatin which information was, at most, immature, unreliable, and misleading. "The FCA defines "'knowingly' to mean actual knowledge that the information was *untrue or deliberate ignorance or reckless disregard of the truth or falsity of that information*.'" United States v. Taber, 342 F.3d 843, 845 (8th Cir. 2003) (quoting United States ex rel. Quirk v. Madonna Towers, Inc., 278 F.3d 765, 767 (8th Cir.2002)). "[I]nnocent mistakes and negligence are not offenses under the Act.... In short, the *claim must be a lie*.'" Id. (quoting Quirk, 278 F.3d at 767) (emphasis added). See also Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1053 (8th

Cir. 2002) ("[I]t is important to remember that the standard for liability [under the FCA] is knowing, not negligent, presentation of false claims."). Indeed, the conduct which Plaintiff alleges on the part of Defendant does not rise to the level of deliberate ignorance, reckless disregard, or falsity. Moreover, the doctors who applied for Medicare reimbursement for off-label uses of Eloxatin could not have lied on the Medicare forms because the Medicare forms did not require that the stage of a patient's cancer be identified. As such, the court finds that Plaintiff's Complaint fails to meet the intent requirement of the FCA.

Further, the court notes that Plaintiff alleges that in November 2002 the WPS added Eloxatin to its policy with broad coverage for treatment of colorectal cancer with Eloxatin, including treatment in the first line and adjuvant settings. Compl., ¶ 16. As WPS is the appropriate Medicare administrator, physicians who sought reimbursement for prescribing Eloxatin for these uses after November 2002 were not acting inconsistently with Medicare regulations. As quoted above, the court in Parke-Davis, 147 F. Supp.2d at 44-45, acknowledged that while in most circumstances a drug must be approved by the FDA for a particular use before Medicare reimbursement is available, such approval is not necessarily a requirement. Plaintiff's Complaint acknowledges that Medicare chose to apply the exception to Eloxatin in November 2002. Thus, because in November 2002 the WPS as the Medicare administrator included off-label uses of Eloxatin for reimbursement purposes, Plaintiff can prove no set of facts to establish that Defendant violated the FCA after that date.

In support of its claims Plaintiff cites Parke-Davis, 147 F. Supp.2d 30. While in Parke-Davis the court found liable pursuant to the FCA a defendant which campaigned with ***false information*** to promote the use of Nuerontin for off-label uses, Plaintiff in the matter under consideration does not allege that Defendant campaigned with ***false*** information. The court in Parke-Davis stressed that the

defendant had a campaign which included instructing its "medical liaisons to make exaggerated and *false claims* concerning the safety and efficacy of Parke-Davis drugs for off-label uses." Id. (emphasis added). In the matter under consideration, however, none of the actions which Plaintiff alleges on the part of Defendant, as delineated above, involve conduct which was designed to present *false* information; rather, according to Plaintiff's pleadings Defendant sought to disseminate data and information from trials and studies. The court finds, therefore, that Plaintiff has failed to plead that Defendant had the requisite intent to violate the FCA and further finds that Plaintiff has failed to state a claim in this regard pursuant to Rule 12(b)(6) and Rule 9(b).

Also, upon acknowledging the "who" requirement of the FCA in regard to pleadings, the court in Parke-Davis, 147 F. Supp.2d at 48, considered that the plaintiff identified physicians who were contacted and given the false information. In the matter under consideration, while Plaintiff identifies both in his Complaint and in his Affidavit the names of persons employed by Defendant who allegedly instructed sales representatives to provide doctors with information on off-label uses of Eloxatin, Plaintiff does not identify doctors whom sales representatives allegedly contacted nor does he identify doctors who allegedly made claims for Medicare reimbursement for off-label uses of Eloxatin. See also Joshi, 2006 WL 52219, at *2 (finding that the complaint alleging a violation of the FCA was insufficient as it failed to identify "the particular" individuals who allegedly provided fraudulently claimed patient care and because it failed to identify the patients who received the services). As such, the court finds that Plaintiff does not meet the requirement of the FCA to plead "who" when alleging fraud.

In regard to the "how" requirement of the FCA, the court in Parke-Davis, 147 F.Supp.2d at 48, found that the plaintiff sufficiently alleged this requirement as he provided specific examples of

allegedly fraudulent statements which the defendant's medical liaisons made to physicians in order to induce the purchase of Neurontin for off-label uses. In a lengthy affidavit which Plaintiff in the matter under consideration submits in opposition to Defendant's Motion to Dismiss, Plaintiff describes meetings which Defendant had with its sales representatives. Plaintiff, however, does not provide examples either in his Complaint or in his affidavit of the allegedly false information which Defendant allegedly gave its sales representatives. Plaintiff specifically states that Defendant's marketing department provided sales representatives with medical monographs containing information on trials including an adjuvant trial and a first line trial, which monographs were to be shown to physicians in the event inquiries were made. Plaintiff further states that the monographs were "slick" and had a "clinical appearance and professional look" and that they "were designed to have the physician focus on a few key elements of the respective trials." Doc. 19, Ex. A, ¶ ¶ 65, 66. Plaintiff also states that Defendant instructed its sales representatives to use the monographs and hand held computers to provide doctors with off-label uses and that sales representatives used the monographs to persuade doctors to avoid a competitor's drug in first line and adjuvant settings.[7] Doc. 19, Ex. A, ¶ ¶ 67, 74. At most, Plaintiff makes conclusory allegations regarding the fraudulent nature of representations made by Defendant and/or by the doctors who sought Medicare reimbursement. See Joshi, 2006 WL 522195, at *3. As such, unlike the complaint in Parke-Davis, the Complaint in the matter under consideration fails to meet the requirement that Plaintiff plead the "how" of the alleged fraud. Because Plaintiff's Complaint insufficiently pleads the "who" and the "how" of a cause of action under the FCA, the court further finds that the Complaint is insufficient

[7] Plaintiff's affidavit is very lengthy and goes into great deal on matters not relevant to whether or not he has sufficiently plead a cause of action pursuant to the FCA. Additionally, it is replete with legal conclusions.

to satisfy the pleading requirements of Rule 9(b). See Parke-Davis, 147 F.Supp.2d at 47-48.

Under the FCA, § 3729(a)(2), not only must a Plaintiff satisfy the requirements set forth above for a claim under § 3729(a)(1), but a Plaintiff must also establish the making or using of false records or statements to cause a claim to be made. The court finds that because Plaintiff has not sufficiently plead a cause of action pursuant to § 3729(a)(1) he necessarily has not sufficiently plead a cause of action pursuant to§ 3729(a)(2). Moreover, Plaintiff has not alleged, other than by his making a conclusory statement, that Defendant made or used a false record or statement to cause a claim to be made to the Government. The court finds, therefore, that Plaintiff's Complaint fails to meet the pleading requirement of both Rule 12(b)(6) and Rule 9(b) in regard to his allegation that Defendant violated § 3729(a)(2). As such, the court finds that Plaintiff's Complaint should be dismissed in regard to his allegations that Defendant violated §§3729(a)(1)-(2).

B. Plaintiff's Claim of a Conspiracy under the FCA, § 3729(a)(3):

Plaintiff alleges that Defendant is liable pursuant to § 3729(a)(3) of the FCA, which section creates liability for persons who conspire to defraud the government through fraudulent claims or payments. To state a claim for conspiracy under the FCA, 31 U.S.C. § 3729(a)(3), a plaintiff must allege: "(1) that the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by United States, and (2) that one or more conspirators performed any act to effect the object of the conspiracy, and (3) that the United States suffered damages as a result of the false or fraudulent claim." Corsello v. Lincare, Inc., 428 F.3d 1008, 1014 (11th Cir. 2005) (citation omitted). "'Allegations that amount to nothing more than an agreement to act lawfully, cannot be actionable claims under the FCA for conspiracy.'" United States ex re. Riley v. St. Luke's Episcopal Hosp., 200 F. Supp.2d 673, 679 (S.D. Tex. 2002), rev'd on other grounds, 355 F.3d 370 (5th Cir.

2004) (citation omitted).

The court first notes that Plaintiff's allegation pursuant to § 3721(a)(3) of a conspiracy between Defendant and physicians who applied for Medicare reimbursement for off-label uses of Eloxatin is inconsistent with his claim that Defendant violated § 3729(a)(1) by providing immature, unreliable, and misleading clinical data to physicians. Moreover, as found above, Plaintiff has not plead facts to suggest that physicians provided fraudulent or false information to the Government or that Defendant provided such information to physicians. The court finds, therefore, that Plaintiff has not alleged the elements of an actionable FCA claim pursuant to a conspiracy theory. Riley, 200 F. Supp.2d at 679. Moreover, Plaintiff has failed to allege facts which suggest that Defendant acted in concert with physicians to make false or fraudulent claims to the Government; rather, Plaintiff makes a conclusory statement which gives Defendant no idea of what acts Plaintiff is accusing it. Under such circumstances a complaint should be dismissed pursuant to Rule 12(b)(6). See Frey v. City of Herculaneum, 44 F.3d 667, 672 (8th Cir. 1995) ("At the very least, however, the complaint must contain facts which state a claim as a matter of law and must not be conclusory."). Likewise, Plaintiff's mere conclusory allegation of a conspiracy does not pass muster under Rule 9(b). See Parke-Davis, 147 F.Supp.2d at 46. The court finds, therefore, that based on the allegations of his Complaint Plaintiff can prove no set of facts to support his allegations of a conspiracy, that Plaintiff's allegation of a conspiracy does not meet the particularity requirement of Rule 9(b), and that, therefore, his Complaint should be dismissed in this regard pursuant to both Rule 12(b)(6) and Rule 9(b). Conley, 35 U.S. at 45-46. [8]

[8] Defendant argues that the court should consider the Government's declining to "take up" supports Defendant's Motion to Dismiss. The Government's decision not to participate

The court notes that its finding that Plaintiff's Complaint should be dismissed is consistent with the purpose of the FCA to encourage individuals who are either close observers or involved in the fraudulent activity to come forward. Indeed, Plaintiff's Complaint does not demonstrate that he has the requisite knowledge for a *qui tam* relator. See Joshi, 2006 WL 522195, at *7.

E. Plaintiff's Request for Leave to Amend the Complaint:

Plaintiff states that while he did not name doctors and healthcare providers on whom he called while employed by Defendant, he could do so by an amended complaint. Plaintiff also suggests that he can add Defendant's power point presentation of July 2003 regarding Eloxatin and related facts to an amended complaint. The court notes, however, that even if Plaintiff were to plead with greater particularity, under no set of circumstances could he establish a violation of the FCA because, as stated above, the information provided by Defendant to Plaintiff, other sales representatives, and/or doctors was not false nor were false claims made to the Government.

Moreover, the most recent pronouncement of the Eighth Circuit in Joshi, 2006 WL 522195, at *6, makes it clear that a *qui tam* complaint must be sufficient at the onset. (holding that Rule 9(b)'s pleading requirement should not be relaxed to allow a *qui tam* plaintiff to "plead generally at the onset and to 'fill in the blanks' following discovery." Additionally, when serving a copy of the complaint on the Government a *qui tam* realtor has the procedural obligation under th FCA to "disclose all material evidence and information known to the realtor in order to allow the government to decide whether or not to intervene." Id. As such, the court finds that Plaintiff will not be permitted to amend his Complaint to plead with greater particularity and that Plaintiff's Complaint should be

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is not a factor for this court's consideration.

dismissed with prejudice.

CONCLUSION

For the reasons more fully set forth above, the court finds that Plaintiff has failed to state a cause of action pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b) and that, therefore, his Complaint should be dismissed in its entirety.

Accordingly,

IT IS HEREBY ORDERED that Defendant's Motion to Dismiss Under Federal Rules of Civil Procedure 12(b)(6) and 9(b) is **GRANTED**; [Doc. 15]

IT IS FURTHER ORDERED that a separate Order of Dismissal shall issue incorporating this Memorandum Opinion.

/s/ Mary Ann L. Medler
MARY ANN L. MEDLER
UNITED STATES MAGISTRATE JUDGE

Dated this 21st day of April, 2006.